DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 2000

Mr. Steven M. Ogilvie
Regulatory and Scientific Affairs Director
SIMS Portex Limited
Hythe
Kent CT21 6JL
ENGLAND

Re: K001555
Wallace Suresample Endometrial Sampler
Dated: July 7, 2000
Received: July 13, 2000
Regulatory Class: II
21 CFR 884.1175/Procode: 85 HHK

Dear Mr. Ogilvie:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

AUG 2 2000

K001555

510(k) SUMMARY

The Summary of Safety and Effectiveness on the Wallace Endometrial Sampler reflects data available and represented at the time the submission was prepared, but caution should be exercised in interpreting the data. The results of future studies may require alterations of the conclusions or recommendations set forth.

Applicant	David Poore Quality Assurance Manager SIMS Portex Ltd Hythe Kent CT21 6JL UK
Telephone	44 1303 260551
Facsimile	44 1303 266761
Date	May 10, 2000
Name	Wallace Endometrial Sampler
Classification	21 CFR 884.1060
Predicate	884.1060 21 CFR Part 884 Obstetrics and Gynecologic Devices
Description	Wallace Endometrial Sampler is a single-use, sterile device for endometrial aspiration biopsy for histological examination or bacteriological culture. The device consists of a polypropylene cannula (260mm long, 3.1mm outer diameter), fitted with a piston for suction, with cm depth markings, elongated side eyes and a formed open end at the distal tip for tissue collection. When fully inserted the piston tip forms a smooth radius with the cannula. For single use only.
Intended Use	Wallace Endometrial Sampler device for endometrial aspiration biopsy
Contraindications	The device should not be used if the patient has the following conditions: Pregnancy or suspect pregnancy. Acute pelvic inflammatory disease. Cervical infections. Blood clotting disorders.
Caution	Only to be used by or under the direction of a qualified person
Technological Characteristics	There are no published standards for these particular types of products, and as such tests have been developed which are considered sufficient to ensure the efficacy and safety of the device(s) for its intended use. Such tests include – Visual; Dimensional; and Functional.
Data Submitted	The biological safety assessment of the Wallace Endometrial has been performed in accordance with the International Standard ISO 10993, Part 1:1994, "Biological Evaluation of medical Devices: Evaluation and Testing." In addition to ISO 10993 the selection of tests, taking into consideration the particular application of the product.

510(k) Number (if known): K001555

Device Name: Wallace Endometrial Sampler

Indications For Use:

Wallace Endometrial Sampler is a single-use, sterile device for endometrial aspiration for histological examination. The device consists of a polypropylene cannula (260mm long, 3.1mm outer diameter), fitted with a piston for suction, with cm depth markings (starting a 40mm mark), elongated side eyes and a formed open end at the distal tip for tissue collection. When fully inserted the piston tip forms a smooth radius with the cannula. For single use only.

CONTRAINDICATION:
The device should not be used if the patient has the following conditions:
Pregnancy or suspect pregnancy.
Acute pelvic inflammatory disease.
Cervical infections.
Blood clotting disorders.

CAUTION:
Only to be used by or under the directions of a qualified person.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use _____
(Per 21 CFR 01.109)

David A. Segman
(Division Sig...
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K001555